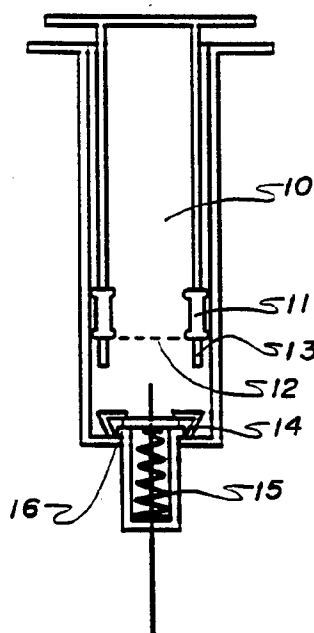




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/24	A1	(11) International Publication Number: WO 94/04207 (43) International Publication Date: 3 March 1994 (03.03.94)
(21) International Application Number: PCT/US93/07729 (22) International Filing Date: 17 August 1993 (17.08.93) (30) Priority data: 07/929,911 17 August 1992 (17.08.92) US (71)(72) Applicants and Inventors: ALLARD, Edward, F. [US/US]; 7830 Greeley Blvd., Springfield, VA 22152 (US). LONGMIRE, Daniel, Q. [US/US]; 519 Courtney Drive, Temple Terrace, FL 33617 (US). (74) Common Representative: ALLARD, Edward, F.; 7830 Greeley Blvd., Springfield, VA 22152 (US).		(81) Designated States: AU, CA, JP, KR, RU, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: METHOD AND APPARATUS FOR A RETRACTING NEEDLE



(57) Abstract

A hypodermic syringe having an automatically retractable needle assembly (15), releasably activated upon voiding the syringe of fluid material. The syringe includes a variable force spring (20), added mass (22) or a friction O-ring (23) to control the speed of the retracting needle (15) upon activation of the release clamps (14) by the plunger extension (13).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

METHOD AND APPARATUS FOR A RETRACTING NEEDLE

DESCRIPTION

5 BACKGROUND OF THE INVENTION

Field of the Invention

The present invention generally relates to automatically retractable hypodermic syringes and blood taking devices, and more specifically to a method and apparatus for controlling the speed of retraction of an automatically retractable hypodermic needle.

Description of the Prior Art

Due to the advent of AIDS and other blood transmittable diseases, it has become extremely important to find a way to safely dispose of hypodermic needles and needles from blood taking devices, such as those shown in U.S. patents 4,838,869, directed to a retractable needle syringe, and 4,838,863, directed to a retractable needle used in collecting body fluids, both having issued to the same inventors hereof.

In some environments, it has been found desirable to control the speed of retraction of the needle during the retraction process. It is not believed that this particular problem has been previously addressed. Some specific issues that must be considered in solving this problem are the

frictional forces being exerted on the needle, the mass of the moving parts, and the friction of flesh on the needle as the needle is removed from the flesh of the patient. One must also consider the effect on the speed of the needle as it tears
5 through the diaphragm of the plunger during the retraction process, keeping in mind that the retracting needle must provide enough force to rupture the diaphragm of the plunger.

SUMMARY OF THE INVENTION

10 It is therefore a primary object of the present invention to provide a method and apparatus for controlling the retraction speed of a needle during the period when the needle is being automatically retracted from the flesh of a patient.

15 Several techniques for accomplishing this purpose are described herein, to include the use of a conical spring, an o-ring or the addition of mass to the needle mechanism to control the speed of retraction of the needle.

BRIEF DESCRIPTION OF THE DRAWINGS

20 The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, in which:

Figure 1 is a cutaway view of one embodiment of an
25 automatically retractable needle assembly; and

Figure 2 shows an embodiment of the needle assembly

of Figure 1, further having means for controlling the speed of retraction of the needle.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

5 Referring now to the drawings, and more particularly to Figure 1, which shows a hypodermic needle, similar to that shown in U.S. patent 4,838,869, wherein a plunger 10 is located inside a hypodermic syringe with a diaphragm 12 attached to the lower end with a slidable seal 11 engaging the inner wall of the syringe. The plunger also has an extension of the plunger wall extending past the diaphragm for contacting release clamps 14, which maintains the spring loaded needle assemble 15 in a readily usable state by engaging a lip 16 of the needle assembly 15, whereby upon
10 termination of the injection process the plunger extension 13 contacts the clamps 14 for releasing the spring loaded needle for irretrievable storage within the plunger housing.

15 Now looking at Figure 2, three separate solutions to controlling the speed of the needle assembly 15 of Figure 1 are depicted, whereby each can be used independently or in
20 any combination.

25 As is obvious from Figure 1, upon release of the clamps 14 holding the needle assembly 15, the assembly will experience an initial sudden movement that accelerates the retraction of the needle assembly and this sudden acceleration can be reduced by using a variable force spring 20, added mass 22 or friction o-rings 23, independently or in any combination.

Looking specifically at the variable force spring 20, a conical spring will meet the necessary criteria and will produce a lower force at the beginning of movement and then increase the force as the spring expands, whereas the helical spring will produce a constant force during its expansion. Using a conical spring for control of the needle movement would apply less of a force at the beginning of movement and consequently reduce the acceleration at the onset of motion. This would accordingly reduce the possibility of any damage to the flesh upon retraction of the needle.

Without enumerating the specific calculations, it is well known that a differential equation representing the motion of a needle retracting from the flesh of a human body can be solved analytically, and shows that the speed of retraction depends directly on the frictional forces of the needle rubbing against the o-ring 23, the mass of the moving parts, and the friction due to the needle pulling away from flesh. In reference to the o-ring type seal, applying more pressure on the needle by using an o-ring having a smaller internal diameter increases friction and consequently slows down the moving needle.

It is possible to apply a pressure that will prevent any retraction, or apply a slight pressure that hardly hampers speed at all. Also, it is possible to reduce spring forces by selecting a weaker spring in order to slow down the needle but this is not a solution for some situations. In the case of the retracting needle assembly, the needle must move fast enough to tear through the diaphragm on the plunger. After tearing through the diaphragm the needle still must be pulled from the human body. The energy in the compressed spring

is used to overcome friction forces , the body friction force, the work of tearing through the diaphragm , and to transfer kinetic energy to the needle assembly. Using the seal as a brake slows down the needle but allows the needle to be withdrawn completely.

The expression for needle movement shows that increasing the mass of the moving parts can be used to slow down the movement. The kinetic energy of the moving parts is given by $KE = mv^2/2$. Clearly, increasing the mass by a factor of say 4, decreases the velocity (speed) by a factor of two. The needles mass can be increased by using a cylindrical mass 22 attached to the needle.

While the invention has been described in terms of a single preferred embodiment, those skilled in the art will recognize that the invention can be practiced with modification within the spirit and scope of the appended claims.

CLAIMS

Having thus described my invention, what I claim as new and desire to secure by Letters Patent is as follows:

- 1 1. In a hypodermic syringe:
2 a fluid holding container;
3 a actuatable plunger within said fluid holding container
4 for forcing the evacuation of any fluids contained therein;
5 an automatically retractable spring loaded needle
6 assembly attached to the distal end of the fluid holding
7 container;
8 a rupturable diaphragm sealing the innermost end of
9 the plunger, whereby upon release of the retractable needle
10 from the needle assembly, the proximal end of the needle
11 ruptures the diaphragm and the needle is projected inside the
12 plunger for storage; and
13 means for controlling the speed of retraction of the
14 retracting needle.
- 1 2. The hypodermic syringe of claim 1, wherein the means for
2 controlling the speed of retraction of the retracting needle
3 comprises a compressed conical spring, coupled to the
4 retractable needle, which will exhibit an increase in force as it
5 propels the needle into the plunger for storage, whereby the
6 speed of the needle is less at the initial release thereof than
7 when the spring is fully extended.
- 1 3. The hypodermic syringe of claim 1 or claim 2, wherein the
2 means for controlling the speed of retraction of the retracting
3 needle includes an o-ring integrally mounted within the
4 needle assembly at the distal end thereof, for passage of the

5 distal end of the needle therethrough, whereby the internal
6 diameter of the o-ring may be selected to provide a frictional
7 force to the shaft of the needle for controlling the speed of
8 retraction of the needle.

1 4. The hypodermic syringe of claims 1 or 2, wherein the
2 means for controlling the speed of retraction of the retracting
3 needle includes an additional mass connected to the needle to
4 absorb some of the kinetic energy stored in the compressed
5 spring, thereby reducing the velocity of the retracting needle.

1 5. A method of controlling the speed of retraction of an
2 automatically retractable needle, including the steps of:
3 actuating a plunger within a fluid holding container;
4 expelling the fluid from the fluid holding container;
5 releasing the retractable needle from a spring loaded needle
6 assembly for storage in the actuating plunger upon contact of
7 the distal end of the actuating plunger and a releasable
8 engagement means functioning to hold said retractable needle
9 in a state of equilibrium within said spring loaded needle
10 assembly;

11 controlling the speed of retraction of the retractable
12 needle upon release from the spring loaded needle assembly,
13 whereby the speed of withdrawal of the distal end of the
14 needle from a patient may be carefully controlled.

1 6. The method as set forth in Claim 5, wherein said step of
2 controlling the speed of retraction of the retractable needle
3 further includes the step of providing a conical spring for
4 maintaining the needle within the spring loaded assembly,
5 which spring exhibits the characteristic of an increasing
6 retracting force after the initial release of the spring loaded
7 needle.

1 7. The method as set forth in Claim 6, wherein the step of
2 controlling the speed of retraction of the retracting needle
3 further includes the step of providing an o-ring within the
4 distal end of the spring loaded needle assembly for applying
5 radial force to the needle to further slow and control the
6 speed of retraction of the needle.

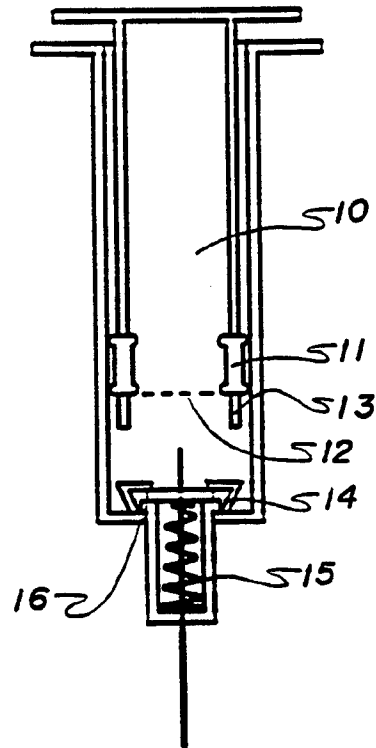


FIGURE 1

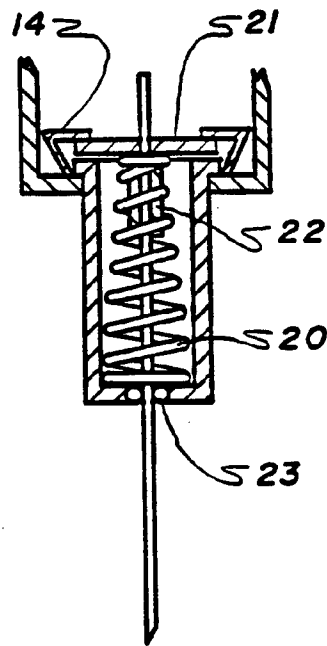


FIGURE 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/07729

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/24
US CL :604/110, 195

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/110, 195,135, 198, 194, 263; 128/919

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Please See Extra Sheet.

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US, A, 4,994,034 (Botich et al) 19 February 1991, See entire document.	1,4/1,5 3/1
X	US, A, 5,053,010 (McGarry et al) 01 October 1991	1 and 5
X	US, A, 5,019,044 (Tsao) 28 May 1991, See entire document	1 and 5
A	US, A, 4,838,869 (Allard) 13 June 1989	None

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 15 September 1993	Date of mailing of the international search report 28 OCT 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JOHN G. WEISS
Facsimile No. NOT APPLICABLE	Telephone No. (703) 305-2702